Remarks

Status of the application and the present response

Claims 1-20 are pending and stand rejected in the application. With entry of the instant response, claim 13 has been canceled without prejudice, and claims 1, 7 and 12 have been currently amended. Specifically, claims 1 and 7 have amended to improve consistency of the claim language by inserting the abbreviated form of the cAMP response element, CRE. Claim 12 has been amended to specify that the three response elements are operably linked to the reporter gene in the reporter construct, which is a claim limitation recited in the canceled claim 13. In addition, the claim 12 has been amended to correct a typographical error. Support for the amendments are replete in the specification. These amendments do not introduce new matter, and should not be construed as acquiescence of any ground of rejections.

The following remarks address issues raised in the instant Office Action.

Rejection under 35 U.S.C. § 102(a)

Claims 1-20 were rejected under U.S.C. § 102(a) as allegedly anticipated by Jiang et al., Anal. Biochem. 316: 34-40, 2003 ("Jiang et al."). Applicants respectfully traverse this rejection.

A rejection under 35 U.S.C. § 102(a) can be properly rendered only if the claimed invention was known, used, patented, or described in a publication by others prior to the subject invention. However, the reference cited in the instant Office Action, Jiang et al., is not a publication that can be properly relied upon to make a rejection under 35 U.S.C. § 102(a). Instead, Jiang et al. reported the same work of the present inventors on which the instant patent application is partially predicated. Specifically, the lead author of Jiang et al., Ms. Cecilia Jiang, and the corresponding author, Dr. Yinghe Hu, are the co-inventors named in the instant patent application. Contribution of the other authors to the cited publication was related to routine technical assistance under the direction and supervision of Dr. Yinghe Hu. As such, the presently claimed invention was not described in a publication "by others" within the meaning of 35 U.S.C. § 102(a). Accordingly, Applicants respectfully request that the instant rejection be withdrawn.

Rejection under 35 U.S.C. § 112 - Written Description

Claims 1-20 were also rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The basis of the rejection, as alleged in the Office Action, is that the multiple response element (MRE), cAMP-response element (CRE) and the serum response element (SRE) recited in the claims are undefined in the specification or the claims. It was also stated in the Office Action that these terms "would embrace any sequence that is labeled an MRE, CRE and SRE," and that "the specification does not disclose any teachings as to the structures of these sequences and how the structures of these sequences relate to their function." It was further stated in the Office Action that "the specification neither described the complete structure of a representative number of species" nor "a representative number of species in terms of partial structure and relevant identifying characteristics." This rejection is respectfully traversed for the reasons stated below.

First, the MRE, CRE and SRE response elements recited in the claims are NOT "any sequences merely labeled "MRE/CRE/SRE" as asserted in the Office Action. To the contrary, they are technical terms that are all well known and recognized in the relevant art. Each of these response elements has well defined function and structure characteristics. For example, SRE was reviewed as a well recognized technical term in the scientific literature as early as 1992. See, e.g., Trends, *The serum response element*, Biochem Sci. 17:423-6, 1992. In addition, the well defined function of this response element is also reflected in its definitions present in several dictionaries (see the attached printout sheets of On-line Medical Dictionary and Dictionary of Cell and Molecular Biology). For example, it is defined in the Dictionary of Cell and Molecular Biology (Online) as "DNA motif found (for example) in the c-fos promoter, which is bound by the serum response factor."

Likewise, MRE and CRE are also scientific terms well recognized by the skilled artisans in the filed of molecular biology. For example, there have been a number of scientific articles devoted to reviewing the structure and function of cAMP response elements since 1994. See, e.g., Vallejo, *Transcriptional control of gene expression by cAMP-response element binding proteins*, J Neuroendocrinol. 6:587-96, 1994; and Habener et al., *cAMP-dependent regulation of gene transcription by cAMP response element-binding protein and cAMP response element modulator*, Vitam Horm. 51:1-57, 1995. CREs from different transcription regulatory systems have since been reported, all with identical function and consensus sequences. Similarly,

the structure and function of MRE was reported in the literature as early as 1989. See, e.g., Ray et al., *A multiple cytokine- and second messenger-responsive element in the enhancer of the human interleukin-6 gene: similarities with c-fos gene regulation*, Mol Cell Biol. 9:5537-47, 1989. MREs from different cells that have been reported in the literature all share common structure feature (i.e., sequences) and identical function in regulating transcription. Thus, rather than embracing any sequence merely labeled MRE/CRE/SRE, each of the three response elements recited in the claims only encompass a limited number of art recognized DNA motifs. In addition to performing the same or similar function in regulating transcription, members in each of the three classes of response elements all share common structure features (more details below).

Applicants further note that, contrary to the statement made in the Office Action, the subject specification has provided ample teachings and description of these response elements. The description of these transcription control elements in the specification is consistent with their well defined functions and structures. Specific structures of representative members of these response elements were also set forth in the specification. For example, it was taught in the specification (e.g., at page 8, line 26 to page 9, line 5) that "serum response elements are promoter elements required for the regulation of many cellular immediate-early genes by growth." The specification also noted that "SREs from various genes (e.g., c-fos gene) have been described in the art, e.g., in Treisman, R., *The serum response element*, TIBS, 17:423-426, 1992." The specification further provided the specific nucleotide sequences of a few SREs, e.g., SEQ ID NO: 1, SEQ ID NO: 2, and SEQ ID NO: 5.

For MREs, the specification (e.g., at page 9, lines 6-17) disclosed that they "are enhancer elements that confer responsiveness to multiple cytokines and second messengers." Two specific examples of MREs and their sequences were also provided in the specification via incorporation of references cited therein. The specification (e.g., at page 9, lines 18-26) also taught CREs are transcription regulatory sequences that interact with transcription factors which mediate signal transduction involving cAMP. It was further disclosed in the specification several exemplary CRE sequences, e.g., TGACGTCA, TTACGTCA, TGACGTCT, TGACGTAG, and CTGCGTCA.

Applicants also urge the Examiner to note that the currently rejected claims are not directed to the SRE, MRE and CRE transcription control elements per

se. Rather, the claims are directed to polynucleotide constructs that comprise these response elements and methods of using such constructs. Patentability of the claimed invention does not preside on the exact sequences of the response elements employed in the polynucleotide constructs. Instead, patentability is predicated on the novel concept of employing all three kinds of response elements in a single construct for detecting activities of different types of GPCRs in a single functional assay. Thus, so long as each employed response element performs its well defined function, the exact nature of the response elements (e.g., their sequences) used in the construct is not essential or critical to the claimed invention. It is readily apparent that any of the art recognized MRE, CRE and SRE elements can be employed to produce the claimed polynucleotide constructs and methods, with the same or similar effect.

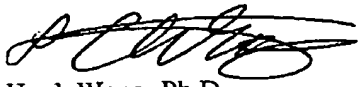
For all clarifications and reasoning stated above, Applicants submit that the subject specification has provided sufficient description of the presently claimed invention. Withdrawal of the instant rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If a telephone conference would expedite prosecution of this application, please telephone the undersigned attorney at 858-812-1539.

Respectfully submitted,



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Result of search for 5974

Welcome, new user.

serum response element

DNA motif found (for example) in the c-fos promoter, which is bound by the serum response factor.

Author: Julian Dow

There were 1 hits for 5974 in 5973 records.

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serum response element

Dyad symmetry element bound by serum response factor to control the expression of c fos.

(18 Nov 1997)

Previous: serum prothrombin conversion accelerator, serum reaction, serum requirement
Next: serum response factor, serum shock, serum sickness, serum therapy